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PATENT AND
TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
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| In re Application of | : |
| CAO et al | : |
| Serial No. 09/404,520 | : Decision on Petition |
| Filing Date: 23 September 1999 | : |
| Attorney Docket No. 16517.081 | : |

This letter is in response to the Petition under 37 CFR 1.144, filed 27 March 2002. The delay in acting on this petition is regretted.

BACKGROUND

This application was filed on 23 September 1999 under 35 USC 111 and discloses 12,000 genes or partial genes of the filamentus fungus *Emericella nidulans* which have been analyzed and arranged into 11,958 predicted genes disclosed as SEQ ID Nos. 16207-28165. The jumbo application is packaged into 41 file wrappers.

In Paper No. 6, mailed 12 February 2001, the original 46 claims were restricted into eleven groups under 35 USC 121. The petition is not concerned with the restriction requirement between the eleven patentably distinct groups, so this matter will not be discussed in this decision.

Within each of the eleven groups, Paper No. 6 went on to make a restriction with respect to the 11,958 patentably distinct, unrelated nucleic acid molecules selected from the groups consisting of SEQ ID Nos. 16207- 28165. Applicants have petitioned for reconsideration of the restriction requirement to a single nucleic acid molecule, within elected Group XI.

In Paper No. 11, filed 3 May 2001, claims 1-28 and 31-46 were canceled. Claims 29-30 were amended. Claims 47-58 were added. Applicants elected Group XI, claims 29, 55-

58 and SEQ ID No. 16207, with traverse. The elected invention, as exemplified by original Claim 29 recites:

> Computer readable medium having recorded thereon at least 100 of the nucleotide sequences depicted in SEQ ID No. 16207 through 27905 or complements thereof.

Claims 55-56 recite computer readable medium and depend upon claim 29. Claim 57 recites a computer based system. Claim 58 recites a method of identifying nucleotide sequence comprising comparing target sequences to a sequence stored in computer readable medium of claim 29.

Applicants' traversal was on the grounds that independent claim requires at least 100 of the nucleotide sequences depicted in SEQ ID No 16207 though SEQ ID No 27905 or complements thereof.

On 23 May 2001, the Office mailed a first action on the merits, as Paper No. 12. The traversal was considered by the examiner but found not persuasive in view of MPEP 803.04. The Office action stated that in view of the large number of applications which require sequence searches, only a single oligonucleotide [sic, nucleotide] search will be performed for each application. The restriction requirement was made Final. Claims 29, 55 and 56 were rejected under 35 USC 101 for lack of utility. Claims 55 and 56 were rejected under 35 USC 112, second paragraph for indefiniteness. On paragraph 7, page 5 of the Office action, claims 57-58 were indicated as allowable, as no references taught or suggested SEQ ID No. 16207. It is noted that claims 57-58 depend upon a non-allowed claim and as such, should have been objected to instead of indicated as allowable. It is also noted that claims 57-58 should have been indicated as allowable, only in part, because the claims encompass non-elected subject matter.

In the response, filed 28 October 2001 as Paper No. 14, Applicants canceled claims 29-30 and 47-56. Applicants amended claims 57 and 58 to recite a system and method limited by the phrase "computer readable medium having recorded therein at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID No. 16207 through SEQ ID No. 27905 and complements thereof." Applicant continued to traverse the restriction requirement, stating that the computer readable medium has a record of at least 100 nucleotide sequences selected from the group consisting of SEQ ID No. 16207 through SEQ ID No. 27905 and complements thereof.

In the Office action, mailed 28 December 2001 as Paper No. 15, Claims 57 and 58 were indicated as pending and objected to on the cover sheet (PTO-326 form). Paper No. 15 stated that "the application contains claims 57 and 58 drawn to an invention non-elected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of non-elected claims to other appropriate action (37 CFR 1.144). See MPEP 821.01." No claims were rejected. The action was made Final.

On 27 March 2002, Paper No. 16, Applicants filed a Petition under 37 CFR 1.144, requesting review and withdrawal of the restriction requirement.

**DISCUSSION**

The application, file history and petition have been considered carefully. Applicants' Petition filed as Paper No. 16 under 37 CFR 1.144 requests that the Commissioner review and withdraw the restriction requirement and require consideration of the patentability of the full scope of the claims. The petition argues that the restriction is overly restrictive and does not follow the directives and standards of the MPEP. The petition argues that the MPEP requires examination of their Markush claims and that applicants are entitled to the 100 sequences selected. The petition argues that applicants have been denied their statutory right to the disclosed invention. These points will be addressed in turn.

The petition is correct in stating that while the MPEP is not law, it is a directive and requires compliance by USPTO employees.

The petition next argues that the restriction requirement was overly restrictive and did not follow the directives of the MPEP. This is not persuasive for the following reasons.

The petition cites MPEP 803.04 including the examples of typical nucleotide sequence claims:

> Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 et seq. (and the partial waiver of 37 CFR 1.475 and 1.499 et seq., see MPEP § 1850) include:
>
> (A) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1-1,000;
> (B) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000; and
> (C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

Applicant then stated that the claims of the instant application are of the type addressed in example (C) above. Applicant is correct in that example (C) most closely resembles the instant claims 57-58. However, there are three important differences between the example (C) as set forth in MPEP 803.04 and the instant claims 57-58. Two of these three differences are relevant to this next section of the discussion.

First, the examples in MPEP 803.04 apply to product claims. The instant application contains both computer system (apparently product) claim 57 and method claim 58.

Second, MPEP 803.04 example (C) recites a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1000. In contrast, claims 57-58 recite "computer readable medium having recorded therein at least 100 nucleotide sequences including sequences selected from the

group consisting of SEQ ID No. 16207 through SEQ ID No. 27905 and complements thereof." The term "including" is open claim language. The medium of claim 57 does not require 100 sequences selected from the group consisting of SEQ ID No. 16207 through SEQ ID No. 27905 and complements thereof. The medium of claim 57 only requires 100 sequences, one or more of which may be selected from the group consisting of SEQ ID No. 16207 through SEQ ID No. 27905 and complements thereof. Thus the argument that 100 sequences are required for the claimed and should be searched is not persuasive, since the argued limitations are not present in the claims as written.

Had the claims been formatted along the lines of example (C), the following section of MPEP 803.04 applies when the claims are comparable to example (C):

> Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such as set forth in example (C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B). More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed

The petition states that, in view of this section, applicants are entitled to have the 100 sequences searched and examined. This argument is not persuasive for several reasons. First, the argued limitations are not present in the claims, as written. Second, nothing in the section cited above requires an examination of all the sequences listed in example (C). To the contrary, the section teaches that claims comparable to example (C) will be subject to a restriction requirement. Further the section teaches that once an allowable sequence is identified, all combinations containing the allowed sequence would then be allowable. In this application, the examiner has indicated SEQ ID No. 16207 to be free of the prior art. As such, any combination requiring SEQ ID No. 16207 would also be free of the prior art.

If the claims were re-written to conform with claim language of example (C), in view of the identification of an allowable sequence, MPEP 803.04 clearly teaches that all combinations containing the allowed sequence would also be allowable. As written, none of the pending claims require SEQ ID No. 16207.

The Petition argues that the Office has denied applicants of their statutory rights in the disclosed invention.

With regard to the burden of searching, the Petition argues, among other things[1], that the added cost of multi-sequence searching is merely a small increment of the cost of a single sequence search. The financial cost involved in the running the computer search alone is not a persuasive reason for rejoining the sequences.

To search each invention, the Office must use each sequence as a query for multiple nucleic acid databases. Once the results from each database are obtained, the Examiner needs to review the nucleic acid alignments, gather relevant references citing the sequences and further search the references with regards to the claimed sequence.

A review of the specification shows that a protein with SEQ ID No. 16248 is similar to a Glutenin; SEQ ID No. 16250 similar to a carboxypeptidase Y; SEQ ID No. 16255, a MHC Class I proline rich protein; SEQ ID No. 16261, a polymerase; SEQ ID No. 16281 a ribosomal protein and SEQ ID NO. 16566, a chitinase. See Table 2. Each of these proteins, and the DNA encoding such, have a different structure and function and are involved in a different pathway within the cells. A polymerase joins nucleic acid subunits together to form nucleic acid molecules. A ribosomal protein translates mRNA into protein. The proteins may be translated at different times of the cell cycle, and the proteins may be located in different organelles in the cells. For those that are enzymes, their substrates and active sites are structurally and functionally distinct.

For the instant application, the nucleic acid database search and literature search, both particularly relevant in this art, are not co-extensive and are much more important in evaluating the burden of search. The results obtained from a search with one sequence would not be co-extensive with the results obtained from searching the same database with another sequence. Further, it is doubted that applicants would readily accept the rejection of the elected invention (SEQ ID No. 16207) over a reference that relates only to the one of the other sequences (SEQ ID Nos. 16208-28165). Clearly different searches and issues are involved in the examination of each group. For these reasons, the restriction requirement to a single nucleotide sequence is deemed to be proper.

The Petition argues that applicants are not claiming nucleotide sequences in isolation, but are claiming a computer based system and a method which allows one to search the genome of the filamentous fungus *Emericella nidulans* for a targeted sequences. By requiring an election of a single sequence, the Petition argues that the value of the invention as a tool is destroyed and that the Office is attempting to rewrite the claims to another invention. The arguments are not commensurate in scope with the claims. None of the claims require more than one of the sequences SEQ ID Nos. 16207-28165. The open language allows the other 99 sequences to be any sequence.

Concerning applicants' argued statutory rights, there is a third important difference between the example (C) as set forth in MPEP 803.04 and the instant claims 57-58:

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[1] The petition also presents a variety of other suggestions for the Office, such as petitioning Congress to amend the law, contracting out sequence searches or accepting applicants' contributions to fund sequence searches, all of which are beyond the scope of this petition decision.

MPEP 803.04 exemplifies composition claims that require actual nucleic acid molecules. MPEP 803.04, example (c) reads upon a set of DNA molecules in a test tube. The instant claim 57 is directed to a computer system (database) requiring computer readable medium (diskette) having recorded thereon the sequence data. Information, such as a sequence data, is considered non-functional descriptive material, and is not considered as a physical entity such as a composition or molecule. Applicants are directed to MPEP 2106 for examination guidelines for computer related inventions.

**DECISION**

The petition is **DENIED** for the reasons set forth above.

Applicants remain under obligation to properly respond to the Final Office Action mailed 28 December 2001, within the time period set therein or as extendable under the provisions of 37 CFR 1.136(a).

No fee is required for this petition. The payment of $130.00 will be refunded to Applicants' deposit account number 50-1824.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, Washington DC 20231 or by telephone at (703) 308-7553 or by facsimile transmission at (7030 308-7230.

John Doll
TC1600 Group Director